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U.S. AGENCY FOR
INTERNATIONAL
DEVELOPMENT

Technical Guidance on the “Comprehensible Information” Paragraph of the Tiahrt Clause

Summary

As a supplement to other guidance on the Tiahrt provision of the FY1999 appropriation, this guidance is specifically intended to help missions understand and implement the section on “comprehensible information” to be provided to clients on their chosen contraceptive method. Agency-supported programs have a longstanding commitment to promoting good client-provider interaction as a key aspect of quality of care and informed choice through a variety of means including counseling, print materials and mass media. These approaches should be applied to the Tiahrt-mandated information. However, in addition, USAID/W strongly recommends a specific tangible (i.e. physical) intervention (e.g. wall charts, flip charts, package inserts) be implemented in all service delivery points of contact, to promote more consistent provision of information.

To help implementation, USAID/W has developed illustrative recommendations on technical information and a wall chart for use in clinics that will help to satisfy the Tiahrt provision. Missions can use these for development of country-specific materials or they can request copies of the wall chart for in-country distribution. We are also working with social marketing contractors to develop appropriate package inserts. With central core funds, USAID/W will make available substantial numbers of wall charts in at least 4 languages (although available core funds are limited.)

Action: As described below, by June 18, 1999, missions are requested to notify USAID/W of their plans for implementing the comprehensible information provision and to send orders for copies of the wall chart.

Background

The paragraph of the Tiahrt clause on “comprehensible information” is as follows:

“The project shall provide family planning acceptors comprehensible information about the health benefits and risks of the method chosen, including those conditions that might render the use of the method inadvisable and those adverse side effects known to be consequent to the use of the method. This requirement may be satisfied by providing information in accordance with the medical practices and standards and health conditions in the country where the project is conducted through counseling, brochures, posters or package inserts.”

While the clause embodies principles of quality that our programs have promoted for years, we also recognize:

Quality goes beyond the Tiahrt provision. For example the provision relates only to the “method chosen” and is silent about other methods. Also, contraceptive methods have a variety of advantages and disadvantages (e.g. cost, or ease of discontinuation) above and beyond health benefits, risks and side effects. Likewise, optimal client-provider interaction is not just the unidirectional provision of information. Rather it is interactive communication where the provider listens to the client, answers specific questions and tries not to burden the client with more information than is useful.

Realistically, communicating information and achieving good client-provider interaction consistently isn’t easy. Improving communication is an ongoing process that calls for long-term efforts.

A Two-Track Approach

Since we are interested in promoting informed choice as well as other aspects of quality and access above and beyond the Tiahrt provision, and at the same time must meet the specific Tiahrt requirements, USAID/W recommends a “two-track” approach. First, continue to promote informed choice and good client-provider interaction through the usual mechanisms— including training, supervision, counseling, mass media, print materials, and other information, education and communication materials such as flip charts and videos. In addition, to ensure that comprehensible information is provided about health benefits and risks, USAID/W recommends a set of specific tangible (i.e. physical) interventions at each service delivery point of contact as follows:

- Clinical Service Sites: A wall chart on the various contraceptive methods clearly posted in all sites.
- Social Marketing: Package inserts or overpackaging with the information pertinent to that method.
- Community Based Distribution (CBD): Suitable job aid(s) and IEC materials, such as a checklist or flip chart, to help convey the Tiahrt-mandated information.

Having such written material clearly visible in a wall chart or package insert or in the hands of CBD workers will permit the project to demonstrate and document that comprehensible information has been provided in a systematic way.

Content

The information attached has been developed by technical staff in USAID/W and the Maximizing Access and Quality (MAQ) Technical Guidance and Competence Subcommittee. First is a chart entitled “*Illustrative Guidance on ‘Comprehensible Information’ Section of Tiahrt Amendment.*” It illustrates the kind of information that should

be provided to each client concerning health benefits, conditions that would make using the method inadvisable, and known side effects (health risks are included in the last two categories). The information has been adapted from the WHO document, *“Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use”* and from Essentials of Contraceptive Technology.*

The second chart: *“Some methods are not advised when certain health conditions are present,”* is a compact presentation of “inadvisabilities” that could be incorporated into a wall chart or brochure.

Both of these charts are a starting point. The information they contain need not be considered either a “floor” or a “ceiling” of information that should be provided to an individual client. Indeed, the Tiahrt clause indicates that the information requirement may be satisfied “in accordance with the medical practices and standards and health conditions in the country where the project is conducted....” Such adaptation is also in keeping with a general principle of quality of care and good counseling -- to tailor information to the specific needs of the client.

Thirdly, we have attached a representation of a **wall chart**. We have provided such a chart along with the clinical guide, Essentials of Contraceptive Technology, (modified to comply with Tiahrt beginning with the Spanish version - printed Spring 1999). This chart has been endorsed by WHO and carries the WHO logo. USAID/W believes that use of the chart will help assure compliance with the Tiahrt requirement and strongly encourages missions and cooperating agencies to consider wide dissemination of the chart, or a locally adapted form of it, in service delivery programs assisted by USAID.

For missions who would like to use this wall chart in their programs, USAID/W has set aside substantial (albeit limited) core funds to print it in at least four languages (English, Spanish, French, and Arabic.) If there is sufficient demand for the wall chart in other languages (e.g. Swahili or Hindi), USAID/W may provide them as well. Missions will have to support in-country distribution and use.

The wall chart is also available electronically in various translations at the following Internet URL: <http://www.jhuccp.org/wallchart>. It can also be obtained from the Johns Hopkins University Population Information Program in other electronic forms and printed form.
Contact:

Stephen Goldstein, Population Information Program
Johns Hopkins Center for Communication Programs
111 Market Place, Suite 310
Baltimore, MD 21202, USA
Fax: (410) 659-6266, E-Mail: PopRepts@jhuccp.org

USAID/W is also working with the Commercial Marketing Strategies (CMS) staff and Population Services International (PSI) to review existing package inserts and overpackaging of social marketing contraceptives to promote compliance with the Tiahrt provision.

Action

Given the importance of compliance with the Tiahrt requirement on comprehensible information, missions are strongly urged to work with host country colleagues to ensure that appropriate tangible interventions as described above (wallcharts, package inserts, and CBD job aids) are deployed in all service delivery contact points subject to the Tiahrt provision (beginning with FY99 Development Assistance funds) in a timely fashion.

- 1) We request that each mission provide USAID/W with a brief indication of how it plans to address each service delivery arena (clinical service sites, commercial/social marketing programs, and community-based distribution programs.)
- 2) For missions who would like to receive wall charts in English, Spanish, French or Arabic, please let us know the number and the language. If you would like us to consider printing the wall chart in another language, please let us know the number and language needed.

Please provide responses by e-mail by June 18 to Joanne Jeffers G/PHN/POP.

If you have further questions after reviewing this guidance, you are encouraged to contact Jim Shelton, Senior Medical Advisor, Office of Population.

*World Health Organization (WHO). *Improving Access to Quality Care in Family Planning. Medical Eligibility Criteria for Contraceptive Use*. Geneva, WHO, Family and Reproductive Health, 1996.

Robert A. Hatcher, et al., The Essentials of Contraceptive Technology. Baltimore, Md., Johns Hopkins University School of Public Health, Population Information Program, 1997.

Illustrative Guidance on “Comprehensible Information” Section of Tiahrt Amendment

- For all methods, preventing unwanted pregnancy provides an important health benefit—protection from the risks of pregnancy and childbearing.
- All methods also have specific personal advantages and disadvantages depending on the client’s needs and point of view. For example, some people find the easy reversibility of oral contraceptives an advantage, while other people find the permanence of vasectomy an advantage.

Main Health Benefits	“Inadvisabilities”	Most Common Side Effects
<u>Combined Oral Contraceptives (COCs)</u>		
<ul style="list-style-type: none"> • Monthly periods regular, lighter and shorter; milder, fewer menstrual cramps. • Can prevent or decrease iron deficiency anemia. • Helps prevent various diseases (including ectopic pregnancy, endometrial and ovarian cancer, ovarian cysts, pelvic inflammatory disease, benign breast disease). 	<ul style="list-style-type: none"> • Breastfeeding less than 6 months. • Pregnant, or 21 days or less after childbirth. • Smoker <u>and also</u> age 35 or older. • Known high blood pressure. • Certain types of repeated severe headaches with other signs. • Certain serious active liver diseases. • Certain uncommon serious diseases of the heart and blood vessels and a few other uncommon diseases. <p>If you have questions, ask your provider.</p>	<p>Nausea and vomiting (upset stomach).</p> <p>Spotting and occasional missed periods.</p> <p>Mild headache.</p> <p>Slight weight gain.</p> <p>Moodiness.</p> <p>Very rare serious side effects.</p> <p>If you have questions, ask your provider.</p>
<u>DMPA Injectable</u>		
<ul style="list-style-type: none"> • Helps prevent various diseases (including ectopic pregnancy, endometrial cancer, uterine fibroids). • Makes sickle cell crises less common and less painful. 	<ul style="list-style-type: none"> • Breastfeeding less than 6 weeks. • Pregnant. • Known severe high blood pressure. • Certain serious active liver diseases and a few other uncommon serious diseases. <p>If you have questions, ask your provider.</p>	<ul style="list-style-type: none"> • Bleeding irregularities including amenorrhea. • Weight gain. • Mild headaches.
<u>Norplant Implants, Progestin-Only Pills (POPs)</u>		
<ul style="list-style-type: none"> • Helps prevent iron deficiency anemia and ectopic pregnancy (Norplant). 	<ul style="list-style-type: none"> • Breastfeeding less than 6 weeks. • Pregnant. • Certain serious liver diseases and a few other uncommon serious diseases. <p>If you have questions, ask your provider.</p>	<ul style="list-style-type: none"> • Bleeding irregularities. • Mild headaches.
<u>Emergency Contraceptive Pills (COCs or POPs)</u>		
	<ul style="list-style-type: none"> • Pregnant. 	<ul style="list-style-type: none"> • Nausea and vomiting.

<u>Copper-Bearing IUD</u>		
<ul style="list-style-type: none"> • Helps prevent ectopic pregnancy. 	<ul style="list-style-type: none"> • Pregnant or 48 hrs. to 4 weeks postpartum. • Sexually transmitted disease (STD) or pelvic infection—now or recently; high STD risk. • Unexplained abnormal vaginal bleeding that suggests pregnancy or an underlying disease, until evaluated. • Certain uncommon conditions of the female organs including anatomical abnormalities. <p>If you have questions, ask your provider.</p>	<ul style="list-style-type: none"> • Longer, heavier bleeding. • Higher risk of pelvic inflammatory disease (PID) if you get an STD. • IUD could come out. • Part of the IUD could go through the wall of the uterus (rare).
<u>Female Sterilization, Vasectomy</u>		
	No medical condition prevents a person from using sterilization. Some conditions call for delay or referral, however. If you have questions, ask your provider.	<ul style="list-style-type: none"> • Pain or discomfort for several days after the procedure. • Very rare serious complications of surgery. If you have questions, ask your provider.
<u>Condoms (Male and Female)</u>		
<ul style="list-style-type: none"> • Prevent sexually transmitted infections (STIs) including HIV, and conditions caused by STIs, as well as pregnancy. 	(none)	
<u>Spermicide</u>		
<ul style="list-style-type: none"> • Helps prevent some STIs and conditions caused by STIs, as well as pregnancy. 	(none)	<ul style="list-style-type: none"> • Urinary tract infection.
<u>Diaphragm, Cap</u>		
<ul style="list-style-type: none"> • Helps prevent some STIs and conditions caused by STIs, as well as pregnancy. 	(none)	<ul style="list-style-type: none"> • Urinary tract infection.
<u>Fertility Awareness-Based Methods & LAM (Lactational Amenorrhea Method)</u>		
	(none)	(none)

--Revised draft box for *Essentials* wall chart--

Some methods are not advised for certain health conditions

Condition	Methods Not Advised
Smoker <u>and also</u> age 35 or older	Combined oral contraceptive pills (COCs)*
Known high blood pressure	COCs. If severe high blood pressure, DMPA.**
Breastfeeding in first 6 months Breastfeeding in first 6 weeks	COCs DMPA, implants, progestin-only pills (POPs)
Certain uncommon serious diseases of the heart and blood vessels, and a few other uncommon diseases; certain active liver diseases.	COCs, POPs, DMPA, implants. Ask your provider.
STI or pelvic inflammatory disease (PID)— now or in last 3 months. High STI risk— for example, you or your sex partner has any other partners.	IUD. Use condoms even if also using another method. (Unusual vaginal bleeding may be a sign of STDs.)
Certain uncommon conditions of female organs	IUD. Ask your provider.
Known pregnancy	COCs, POPs, DMPA, implants, IUD. COCs in first 21 days after childbirth.

*Also applies to combined (monthly) injectables throughout.

**DMPA = DMPA injectable (*Depo-Provera*); also applies to NET EN injectable (*Noristerat*) throughout.

Note: Also consult national standards for specific guidance.

5/11/99

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